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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------------|
| 10/771,803 | 02/04/2004 | Lutz Freitag | 000160.0001 | 3335 |
| 32042 | 7590 | 06/14/2007 | | |
| PATTON BOGGS LLP 8484 WESTPARK DRIVE SUITE 900 MCLEAN, VA 22102 | | | EXAMINER MITCHELL, TEENA KAY | |
| | | | ART UNIT 3771 | PAPER NUMBER |
| | | | MAIL DATE 06/14/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/771,803

Applicant(s)

FREITAG, LUTZ

Examiner

Teena Mitchell

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/4/04; 1/20/06; 3/23/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration **acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.**

Applicant has made a duty to disclose statement however the statement is incorrect. Applicant's states, "...is material to **the examination**..." Note the correct statement above.

It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 8/11/03. It is noted, however, that applicant has not filed a certified copy of the German 20/40963-001 application as required by 35 U.S.C. 119(b).

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: sensor 3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any

amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the double-lumen design for the catheter must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because the abstract is longer than 150 words. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: On page 6, line 2, "...150mm..." should be --50ml--.

Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennarsten (6,694,978).

Regarding claim 1, Bennarsten discloses a high-frequency (HFO) ventilator with sensors for detecting spontaneous breathing (16, 15), which identifies the end of inhalation, and administers an additional amount of oxygen to the lungs (Col. 2, lines 50-67 through Col. 3, lines 1-51). The claimed method steps would have been obvious because they would have resulted from the use of the HFO ventilator of Bennarsten.

Regarding claim 2, Bennarsten disclose a HFO ventilator fully capable of delivering the additional amount of oxygen at the end of the inhalation process (Col. 3, lines 1-51; Col. 5, lines 24-62).

Regarding claim 3, Bennarsten does not expressly state the claimed volume of oxygen to be delivered. However, it would have been an obvious matter of design consideration to one of ordinary skill in the art at the time the invention was made because the amount of oxygen to be delivered to a patient would depend on the status of the patient (i.e., infant, adult, age of the patient, and the disease process of the patient) all the factors would be weighed in for the health care person to deliver the proper amount of oxygen to the patient.

Regarding claim 4, note rejection of claim 3 above.

Regarding claim 5, Bennarsten discloses braking the exhalation process of the patient with countercurrent (based upon the valve (9) opening or closing; Col. 3, lines 1-67 through Col. 4, lines 1-16).

Regarding claim 6, Bennarsten discloses braking the exhalation process of the patient with countercurrent (based upon the valve (9) opening or closing; Col. 3, lines 1-67 through Col. 4, lines 1-16).

Regarding claim 7, Bennarsten discloses an oxygen pump (4) operatively connected to an oxygen source (7), the apparatus further comprising sensors (16, 15) for detecting the spontaneous respiration of the patient; the sensors (16, 15) are connected to a control unit (14) for activating the oxygen pump.

Regarding claim 13, Bennarsten discloses a piston pump (4).

Regarding claim 17, Bennarsten discloses the claimed invention except for additional respiration sensors. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have additional respiration sensors, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 183 USPQ 8.

Claims 8-12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennarsten (6,694,978) in view of Hebeler, Jr. (5,054,484) and Whitwam et.al. (4,644,947).

Regarding claim 8, Bennarsten discloses the claimed invention except for a tracheal prosthesis. Hebeler teaches a tracheal prosthesis (Figs. 1, 2). It would have been obvious to one of ordinary skill in the art to substitute the ET of Bennarsten to employ any well known breathing tube such as the tracheal prosthesis as taught by Hebeler as mere substitutions one breathing tube for another because it is well known in the art that if a patient has to stay on a breathing device for an extended period of

Art Unit: 3771

time a tracheal prosthesis is placed because the patient can get tissue breakdown and vocal cord damage after the use of an ET for an extended period. Another difference between Bennarsten and claim 8 is a catheter connectable with the tracheal prosthesis. Whitwam teaches a connection for a jet catheter (11) providing a means for ventilation of any patient at any frequency and tidal volume and safe, with any chosen low pressure conditioned and humidified respiratory gas including volatile anaesthetic vapors (ABSTRACT). It would have been obvious to one of ordinary skill in the art to modify the tracheal prosthesis of Hebeler to a connection for a jet catheter (11) because it would have provided a means for ventilation of any patient at any frequency and tidal volume and safe, with any chosen low pressure conditioned and humidified respiratory gas including volatile anaesthetic vapors as taught by Whitwam.

Regarding claim 9, Bennarsten discloses sensors associated with the ET therefore if you substitute the ET of Bennarsten with a tracheal prosthesis the sensor would still be associated with the support body of the tracheal prosthesis.

Regarding claim 10, Bennarsten discloses sensors on an inner wall therefore if one substitutes the ET of Bennarsten with a tracheal prosthesis the sensor would be on an inner wall as disclosed by Bennarsten.

Regarding claim 11, Bennarsten modified by Whitwam teaches the end of the catheter located in the support body deflected approximately parallel to its longitudinal axis (L) and is provided on the end with a jet nozzle (Figs. 1-8).

Regarding claim 12, Bennarsten modified by Whitwam teaches the end of the catheter located in the support body deflected approximately parallel to its longitudinal axis and is provided on the end with a jet nozzle (Figs. 1-8).

Regarding claim 14, Bennarsten discloses a piston pump (4).

Regarding claim 15, Bennarsten modified by Whitwam teaches a double-lumen design (15, 11 based upon a broad interpretation by the examiner with respect to a double lumen design because Whitwam teaches more than one lumen Whitwam is readable upon the claimed language).

Regarding claim 16, Bennarsten discloses a piston pump (4).

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hebeler, Jr. (5,054,484) in view of Whitwam et.al. (4,644,947) and Bennarsten (6,694,978).

Hebeler in a tracheal prosthesis (10) discloses a tubular body (Figs. 1, 2). The difference between Hebeler and claim 9 is a connection for a jet catheter. Whitwam teaches a connection for a jet catheter (11) providing a means for ventilation of any patient at any frequency and tidal volume and safe, with any chosen low pressure conditioned and humidified respiratory gas including volatile anaesthetic vapors (ABSTRACT). It would have been obvious to one of ordinary skill in the art to modify the tracheal prosthesis of Hebeler to a connection for a jet catheter (11) because it would have provided a means for ventilation of any patient at any frequency and tidal volume and safe, with any chosen low pressure conditioned and humidified respiratory gas including volatile anaesthetic vapors as taught by Whitwam. Another difference

between Hebeler and claim 9 is at least two sensors coupled with the support body. Bennarsten teaches sensors on an ET (16, 15) providing a means to receive output signals for, flow and pressure to detect changes induced by a spontaneous breathing effort (Col. 3, lines 1-21). It would have been obvious to one of ordinary skill in the art to place at least two sensors on the support body of Hebeler because placing the sensors on the body would provide a means to receive output signals for flow and pressure to detect changes induced by a spontaneous breathing effort as taught by Bennarsten.

Regarding claim 20, it would have been an obvious matter of design consideration to one of ordinary skill in the art to have at least one sensor coupled with the inner wall of the support body. Inasmuch as Bennarsten teaches a sensor in the distal end of the ET on an inner wall of the ET, which allows one to be better able to measure the small pressure changes induced by a spontaneous breathing patient. Therefore having the sensor coupled to an inner wall is deemed to be a design consideration, which fails to patentably distinguish over the prior art of Hebeler modified by Bennarsten.

Regarding claim 21, Whitwam teaches the catheter (11) operatively coupled to the support body (Figs. 1, 2).

Regarding claim 22, note rejection of claim 21 above.

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitwam et.al. (4,644,947) in view of Bennarsten (6,694,978).

Regarding claim 23, Whitwam discloses a catheter having a first and a second end (Figs. 1-8). The difference between Whitwam and claim 23 is at least one sensor.

Bennarsten teaches sensors on an ET (16, 15) providing a means to receive output signals for flow and pressure to detect changes induced by a spontaneous breathing effort (Col. 3, lines 1-21). It would have been obvious to one of ordinary skill in the art to place at least two sensors affixable to the catheter of Whitwam because placing the sensors on the body would provide a means to receive output signals for flow and pressure to detect changes induced by a spontaneous breathing effort as taught by Bennarsten.

Regarding claim 24, Whitwam discloses wherein the at least one end comprises a jet nozzle (Figs. 1-8; at 11).

Regarding claim 25, Whitwam discloses wherein the at least one end has a curved course (Figs. 1-8).

Regarding claim 26, Whitwam discloses wherein the at least one end has a curved course (Figs. 1-8).

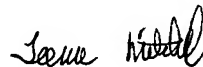
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show respiration devices; 7,156,090; 6,532,960; 5,937,853; 5,954,050; 3,721,233.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Teena Mitchell
Primary Examiner
Art Unit 3771
June 6, 2007

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